Maximizing Efficiency of Research Pharmacy Services: The VA New York Harbor Healthcare System Experience

David Hoffman, RPh, PhD, Simona Peker, RPh, MS/MLS, MSA, PharmD, and Joseph Aprile, RPh, MS

These authors discuss their process of consolidating two research pharmacies, including how they designed a fee-based system to cover research-related expenses.

In today's environment of increased competition and budget restrictions, centralizing health care services is considered a desirable administrative step. This usually results in simplified procedures, increased efficiency, an increase in both patient and provider satisfaction, and reduced operating expenses.

When the VA New York Harbor Healthcare System (VANYHHS) was formed in order to consolidate two VA medical centers (VAMCs), considerable duplication of the services provided by the two separate research pharmacies was found. We therefore proposed a consolidation of services as a way to save on costs and improve efficiency and quality of service. We also enacted a program in which the research pharmacy charges principal investigators (PIs) in order to cover research-related overhead expenses.

Here, we discuss our review and consolidation of the two research pharmacies, as well as the fee schedule that has been put into action. Although consolidation of services in health care systems has been described before,[1–7] this is the first published report of consolidating two research pharmacy services in the VISN 3 Network.

Dr. Hoffman is a research pharmacy specialist, **Dr. Peker** is the pharmacy site manager, and **Mr. Aprile** is the chief of the pharmacy program, all at the VA New York Harbor Healthcare System, New York.

FORMATION OF THE VANYHHS

Historically, the New York VAMC, the James J. Peters VAMC, and the Brooklyn VAMC, located in the three boroughs of Manhattan, Bronx, and Brooklyn, respectively, were operating as independent entities. In 2001, however, the VA Central Office decided to consolidate the Manhattan and Brooklyn facilities into one administrative unit. The St. Albans Primary and Extended Care Center—which was administratively a part of the Brooklyn VAMC, though located in Queens—was included in the consolidation. The three sites combined to form the new VANYHHS. (The James J. Peters VAMC remains separate from this consolidated system.)

The VANYHHS is part of VISN 3. The VA health care system is organized into 22 VISNs nationwide, with each serving as a regional administrative unit comprised of a few medical centers.

A LOOK AT THE PHARMACY STRUCTURES

The consolidation resulted in one system with two research pharmacies and two research pharmacists—one each at the Brooklyn and Manhattan campuses. To determine the workload and the duties of the research pharmacist at each campus, a review was conducted in cooperation with the pharmacy site manager of the Manhattan campus and the chief of the pharmacy program.

The review showed extensive duplication. Both research pharmacists attended meetings of the Internal Review Board and the research and development and the quality assurance committees. Both filed monthly reports for their campuses. In addition, both performed "routine" research pharmacy functions, such as dispensing medications, inventory control, and handling administrative issues. It was decided that the rational course of action was to have one research pharmacy provide services to both campuses.

This decision raised the question of which campus would provide the services. The review showed that the Brooklyn campus had an average of 10 studies undergoing and six prescriptions dispensed per month. The Manhattan campus had an average of 50 studies undergoing and 500 prescriptions dispensed per month. Thus, the majority of the research and the associated workload originated at the Manhattan campus.

Furthermore, at the Brooklyn campus, the drugs being used for research studies were stored in the main narcotic vault, but the Manhattan campus had a three-room secured space inside the main pharmacy. It was physically separate from the other sections of the pharmacy and it had an electronic security system in place. Based on these observations, it was decided that the Manhattan campus would be the site of the research pharmacy.

ADDRESSING CONCERNS

Before the consolidation was implemented, a meeting was held with the PIs and study coordinators to discuss the proposal. All participants agreed that the consolidation was a rational and cost saving measure. The study personnel based at the Brooklyn campus expressed concern, however, about the delivery of study medications to their campus. After discussing and evaluating different suggestions, it was decided that, whenever possible, the medications would be shipped to study patients using a next-day delivery service. When medications had to be picked up, they would be transferred to the Brooklyn campus by the intercampus shuttle. If necessary, a Manhattan campus pharmacy technician, or other available pharmacy personnel, would hand deliver the medications to the Brooklyn campus.

The research pharmacy at the Manhattan campus was redesigned to create additional storage space. Files that were not accessed on a daily basis were transferred to the secured, high cost inventory room and shelves were rearranged to create storage space dedicated to the Brooklyn-based studies.

Following these adjustments, study medications were transferred from the Brooklyn to the Manhattan campus. This step cleared up valuable storage space at the Brooklyn campus narcotic vault. Sponsors of ongoing Brooklyn-based studies were notified of the change so that replacement medication stocks would be shipped to the Manhattan campus.

ESTABLISHING THE FEE-BASED SCHEDULE

Once the research pharmacy services were centralized and the same standards were established for the two campuses, we decided it was the right time to ask PIs to reimburse the research pharmacy for its overhead expenses. Before implementing this policy, we called staff at a few VAMCs to obtain input on how it was being done at other sites.

Three approaches emerged: (1) the research pharmacy did not seek reimbursement for its services; (2) PIs were being charged a flat fee per study, regardless of the study's size or complexity; or (3) the charge to the PI was calculated based on the number of prescriptions dispensed and the study's complexity.

In our opinion, the first approach was not viable. Without reimbursement, overhead expenses are not covered, thus limiting the quality of services that the research pharmacy can offer to the PIs, as well as to the patients at all three campuses of the VANYHHS. Money collected through reimbursement fees could be used to buy necessary equipment, such as fax machines and refrigerators. Reimbursement fees also would ensure expansion and growth of the research pharmacy in the long run.

The second approach had the advantage of simplicity, as it does not require any calculations or accounting work. We decided to try it. We brought the issue up for discussion at a meeting of the VANYHHS Quality Assurance Committee for Research and Development. All committee members supported the idea of reimbursing the research pharmacy for its overhead expenses. Most committee members (including those involved in active research), however, felt that a flat fee would unfairly discriminate against researchers with small studies. The committee recommended that the research pharmacy adopt the third approach instead.

Subsequently, we looked at fee schedules used at other VAMCs. We also discussed the issue with PIs at our site to establish a reasonable breakdown and range of fees that would be acceptable to most researchers. This resulted in our current reimbursement schedule (Table). As an example, for a "regular" one-year study involving 15 patients, the research pharmacy reimbursement amounts to $6,900. For a "complex" study with the same number of patients and same duration, the reimbursement amounts to $11,040. The fee schedule is posted on the VANYHHS intranet (vaww.nyharbor.med.va.gov/documents/rd/idmf.doc). It will be updated periodically to account for increases in medication costs and inflation.

The general objection raised against the "pay per prescription" approach was that it required a lot of accounting work by the research pharmacist, which was very time consuming. Once we began charging for dispensing prescriptions, however, study coordinators started keeping detailed records. In fact, the usual procedure now is for study coordinators, at the end of a study, to submit to the research pharmacy a spreadsheet that includes the number of prescriptions dispensed to every study patient and to calculate the charges themselves. Initially, we double checked the numbers reported on the spreadsheets and the charges, but we have found them to be in

Table. Fee schedule for the research pharmacy at the VA New York Harbor Healthcare System

Fee type	Fee amount	Research pharmacy services taken into account when assigning fee amount
Start-up fee	$600/protocol	• Review protocol • Clarify protocol with principal investigator and study coordinator • Coordinate dispensing procedures • Enter study drugs into computer system • Prepare and collect required documents • Set up study binders • Set up electronic inventories • Set up sponsor and VA paper inventories • Prepare proper storage for refrigerated or controlled drugs • Receive and process initial shipment of study drugs
Closing fee	$360/protocol	• Final visit by study monitor • Reconcile dispensing inventories with monitor's records • Reconcile returned drugs inventories with monitor's records • Generate closeout and shipping papers • Pack and ship drugs to sponsor • Prepare paperwork and shipment for archiving in VA central storage in Missouri
Dispensing fee	• $276/patient/year (regular studies) • $552/patient/year (complex studies)	• Examples of complex studies include oncology studies and those that require compounding, preparation of IVs, or random assignment of patients by the pharmacy • Fee was calculated assuming an average of three prescriptions per month per patient and a filling time of 15 minutes per prescription and taking into account pharmacist's salary
Maintenance fee	$120/patient/year	• Process orders and receipts of drug replenishment stock • Maintain dispensing records • Maintain records of returned drugs • Oversee the study monitor's site visits • Provide drug-related support (allergies, interactions, etc.) • Provide administrative support and problem solving • Participate in internal review board, research and development, and quality assurance meetings

excellent agreement with the research pharmacy records. Now, we feel confident that we can use the charges calculated by the coordinators, with only a random verification for quality assurance purposes.

As part of the approval process for proposed research studies, we now ask the PIs to allocate a "pharmacy support" budget. We don't usually encounter resistance on this issue, as the overwhelming majority of studies at our site are supported either by a sponsor or a grant. The PIs request the money from the sponsors, or the grant issuing agencies, and include it in their overall research budget.

We intend to seek feedback from the PIs as this program develops further, with the aim of modifying and improving the process. Any improvements or modifications in the current process will be published to assure that the information is available for those interested in this subject.

OUR OVERALL EXPERIENCE

Some negative consequences of consolidation have been pointed out,[1,2] such as the creation of big and cumbersome systems that are difficult to manage and problems arising from handling personnel with dif-

ferent backgrounds and different company cultures.[3,4] These factors, however, were not an issue in our setting. Consolidating the two research pharmacies and centralizing the pharmacy-related research services resulted in cost savings and improved efficiency. For example, reassigning the second research pharmacist to perform other functions within the pharmacy department prevented the need to hire additional staff, saving approximately $100,000 per year in salary. In addition, valuable storage space has been added at the Brooklyn campus narcotic vault.

Both campuses now operate under the same standards. The planning of new studies and the administration of active studies have been simplified. Any questions or concerns PIs and study coordinators may have now need be discussed with only one research pharmacist.

The research pharmacy reimbursement program generates money that may be used to cover research pharmacy overhead expenses and buy necessary equipment. Furthermore, a centralized, well organized, and efficient research pharmacy is more likely to do well in the competition to bring more research projects to the health care system. ●

Author disclosures

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